REMARKS

Claims 4, 13, 45, 46 and 50 were previously pending in the application. Claims 4, 13, 45, 46 and 50 were rejected. Claim 45 is cancelled. Claims 4, 13, 46 and 50 are currently pending. The claims are limited to a "naturally occurring" protein antigens as suggested by Examiner in the Office action. This is a narrowing amendment in line with suggestions in the Office action.

Claim Rejections- 35 U.S.C. §112

1. Claims 4, 13, 45, 46 and 50 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claim 45 is cancelled. Claim 4 has been amended so as to clarify that the composition consists of a single naturally occurring 16 (±4) kDa protein antigen isolated from *Sarcocystis neurona* and a single naturally occurring 30

(±4) kDa protein antigen isolated from *Sarcocystis neurona* in a pharmaceutically accepted carrier. Claims 13, 46 and 50 are amended such that these methods utilize this composition to treat the equine with the *Sarcocystis neurona* infection. The Claims are amended to be directed to compositions consisting of a single naturally occurring protein antigens which are isolated from *Sarcocystis neurona*, and not directed to polypeptide fragments, recombinant polypeptides or fusion polypeptides. While the claims are still directed to the isolated form of the naturally occurring proteins, it is believed that the written description requirement of 35 U.S.C. §112, first paragraph is satisfied by these amendments.

The 16 (±4) and 30 (±4) kDa antigens are described by their physical properties, not merely by function. The 16 (±4) and 30 (±4) kDa antigens are described by their source (isolated from *Sarcocystis neurona*), by their molecular weight as determined by SDS gel electrophoresis, by their ability to bind particular antibodies in antisera from horses infected with *Sarcocystis neurona*, and by their ability to bind monoclonal antibodies prepared against them. These physical properties convey sufficient information

about the antigens to distinguish them from the other proteins of *Sarcocystis neurona*. There is no need to know the amino acid sequence of the antigens or the nucleotide sequence encoding the antigens. The specification describes the 16 (±4) and 30 (±4) kDa antigens by their respective mobilities on SDS polyacrylamide gels (Page 36, lines 22-27 of the specification; U.S. Serial No. 09/156,954, which is now U.S. Patent No. 6,153,394, incorporated by reference on page 13, lines 16-17 of the specification) and two-dimensional gels (Specification: page 33, lines 29-34), by their ability to bind antibodies in antisera from horses infected with *Sarcocystis neurona* (U.S. Patent No. 6,153,394), and by their inability to bind antibodies from other *Sarcocystis* species (Page 13, lines 20-21 of the specification).

The specification further teaches in Example 1 that the 16 (±4) and 30 (±4) kDa antigens were isolated by two-dimensional gel electrophoresis (page 33, lines 29-34) and teaches a method for preparing monoclonal antibodies using the purified 16 (±4) and 30 (±4) kDa antigens. The monoclonal antibodies can be used to identify the 16 (±4) and 30 (±4) kDa antigens (Example 1 at page 33, line 20 of

the specification). Therefore, a person of ordinary skill in the art following the teachings in the specification of the present application would be able to identify and isolate the 16 (±4) and 30 (±4) kDa antigens of *Sarcocystis neurona*. Furthermore, the applicants are not claiming the 16 (±4) and 30 (±4) kDa antigens *per se*. They are claiming a composition that consists of naturally occurring protein antigens, which can be isolated by described methods from a known source. The written description is believed to be adequate without the necessity of providing the amino acid sequence of the proteins comprising the composition. Reconsideration of the rejection is requested.

Claim Rejections- 35 U.S.C. §102

2. Claims 4, 13, 45 and 46 are rejected under 35 U.S.C. § 102(b) as being anticipated by Liang *et al*.

Claim 45 is cancelled. Claim 4 has been amended so as to be directed to a composition consisting of a single naturally occurring 16 (±4) kDa protein antigen isolated from *Sarcocystis neurona* and a single naturally occurring 30 (±4) kDa protein antigen isolated from *Sarcocystis neurona*

in a pharmaceutically accepted carrier. Claims 13, 46 and 50 are amended such that the methods utilize this composition. It is believed that this amendment overcomes the U.S.C. § 102(b) rejection.

According to MPEP 2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The cited prior art reference does not teach or suggest all of the limitations of the claimed composition and methods. Liang *et al.* does not teach a composition consisting of naturally occurring 16 (±4) kDa *Sarcocystis neurona* antigen and an isolated 30 (±4) kDa *Sarcocystis neurona* antigen in a pharmaceutically accepted carrier.

Liang *et al.* teaches that serum and cerebrospinal fluid (CSF) obtained from horses with a clinical diagnosis of a neurologic disorder resembling equine protozoal

myeloencephalitis (EPM) reacted with combinations of Sn30, Sn16, Sn14, and Sn11 proteins extracted from *Sarcocystis neurona* merozoites to form various band patterns on an immunoblot. Liang *et al.* then performs an immunoprecipitation experiment to determine whether the Sn16 and Sn14 are surface proteins (Liang *et al.*: page 1836, second paragraph). Liang *et al.* immunoprecipitated biotin-labeled proteins from a lysate of biotin-labeled merozoites using serum from a horse with a histologically confirmed case of equine protozoal myeloencephalitis (EPM). The immunoprecipitated proteins were separated by SDS-PAGE, electrotransferred to nitrocellulose (NC), and visualized by developing the blot with a peroxidase-streptavidin conjugate probe. The resulting band pattern is illustrated in lane c of Figure 3A. Liang *et al.* then offers Figure 3 as evidence for the surface localization of the Sn14 and Sn16 proteins (Liang *et al.*: Figure 3). Liang *et al.* however, does not teach a composition consisting of a naturally occurring 16 (±4) kDa *Sarcocystis neurona* antigen and a naturally occurring 30 (±4) kDa *Sarcocystis neurona* antigen with or without a pharmaceutically accepted carrier. The immunoprecipitated mixture contains the Sn14 antigen.

Liang *et al.* teaches a lysate having all proteins which are extracted from *Sarcocystis neurona* merozoites. The Coomassie blue stained proteins following SDS-PAGE are illustrated in Figure 3A, lane a. Liang *et al.* also describes biotin-labeled proteins immunoprecipitated from a lysate of biotin-labeled merozoites using serum from a horse with a histologically confirmed case of equine protozoal myeloencephalitis (EPM). As can be seen in Figure 3A, lane c, the immunoprecipitated mixture contains the Sn14 antigen. Liang *et al.* however, does not teach a composition consisting of a naturally occurring 16 (±4) kDa protein antigen isolated from *Sarcocystis neurona* and a naturally occurring 30 (±4) kDa protein antigen isolated from *Sarcocystis neurona* either with or without a pharmaceutically accepted carrier.

In regards to Claims 13, 46 and 50, Liang *et al.* also does not describe administering the claimed composition to an equine to treat the equine with the *Sarcocystis neurona* infection. Liang *et al.* teaches that "S. neurona infection of the horse induces production of antibodies to Sn16 and Sn14, indicating that these two proteins are expressed in vivo and are strong immunogens in the horse."

(Liang *et al.*: page 1837, last paragraph). Liang *et al.* concludes that the Sn16 and Sn14 warrant further investigation as candidate antigens for inclusion in vaccines against *S. neurona* infection. However, Liang *et al.* does not show or suggest administering a mixture to an equine having the Sn30 antigen. While Liang *et al.* concluded that the Sn16 and the Sn14 antigens warrant further investigation as candidate antigens for inclusion in vaccines against *S. neurona* infection, Liang *et al.* does not show or suggest administering to an equine a composition having the 30 kDa Sn30 antigen as claimed by Applicants.

The serum and CSF samples were grouped together by Liang *et al.* based upon the immunoblot band patterns. Liang *et al.* teaches that *in vitro* neutralization assays against *Sarcocystis neurona* merozoites isolated from bovine turbinate cell culture revealed "significant differences in inhibitory activities between the groups of serum and CSF samples with different immunoblot band patterns" (Liang *et al.*: page 1837, first full paragraph.) However, when Liang *et al.* correlated band patterns with inhibitory activities it was concluded that "no inhibitory activity correlating with antibody to Sn30 was noted." (Liang *et al.*: page 1836,

first paragraph.) This can be clearly seen with sample N6 which recognizes the Sn30 protein of *Sarcocystis neurona*. (Liang *et al.*: Figure 2 on page 1836.) The teaching of Liang *et al.* therefore, does not show or even suggest to a person of ordinary skill in the art that a composition consisting of naturally occurring 16 (±4) kDa and 30 (±4) kDa *Sarcocystis neurona* antigens should be pursued for the treatment of an equine having a *Sarcocystis neurona* infection. A person of ordinary skill in the art would not be motivated to pursue the claimed composition and method of using the composition after reading Liang *et al.* Liang *et al.* would actually lead a person of ordinary skill in the art away from the claimed invention, since *in vitro* neutralization assays against *Sarcocystis neurona* merozoites show that the Sn30 antigen provides no inhibitory activity. In light of these amendments, the Claims are patentable over Liang *et al.* Reconsideration of the rejection is requested.

The written description is believed to be adequate and the cited reference does not teach all of the elements of the present invention. Therefore, in light of the above, it is now believed that Claims 4, 13, 46 and 50 are patentable and in condition suitable for allowance. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully,

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